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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,142	05/10/2001	Ilse Bartke	305J-900320US	6801

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EXAMINER	
WEBER, JON P	

ART UNIT	PAPER NUMBER
1651	16

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/854,142	BARTKE ET AL.	
	Examiner	Art Unit	
	Jon P Weber, Ph.D.	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,12-15,17,19-23 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,12-15,17,19-23 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *15*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's IDS submission filed on 29 December 2003 has been entered and considered.

Claims 1, 3-6, 12-15, 17, 19-23 and 25 have been presented for consideration on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Claim 20 is objected to because of the following informalities: "encephalmyelitis" is a misspelling. Appropriate correction is required.

Claim Rejections - 35 USC § 102

Claims 1, 12, 17, 19, 23, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Kramer et al. (1995).

Kramer et al. (1995) disclose that "Unexpectedly, exogenous NGF profoundly changes development of the demyelinating inflammatory changes evoked by neuritogenic T lymphocytes during the course of EAN. The reduction of clinical symptoms through the entire course of the disease by using NGF-secreting R4 lymphocytes is fathfully reflected in a corresponding amelioration of lesions in the PNS." (See page 1164, column 2, first full paragraph).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-6, 12-15, 17, 19-23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kramer et al. (1995) in view of Urschel et al. (1990) and Althaus (WO 9303140) and further in view of Unger et al. (EP 731,108) and Unger et al. (1995).

The teachings of Kramer et al. (1995) have been discussed above. Kramer et al. (1995) do not teach adding a protease inhibitor, human, the specific amount, or how to administer NGF.

Urschel et al. (1990) disclose that suppression of NGF endogenous levels with anti-NGF antibodies results in demyelination. Hence, restoring normal levels of NGF suppresses demyelination by being necessary for normal myelination.

Althaus (WO 9303140) discloses that a pharmaceutical composition comprising NGF or an active fragment thereof can be used as a treatment for diseases in which demyelination of

nerve fibers occurs (page 4, second paragraph). Some of these diseases included are set forth in the paragraph connecting pages 4-5. Specific active fragments include NGF-ß, NGF-2.5S, and NGF 7S (page 2, third full paragraph). The NGF-ß may be human recombinant. The compositions may further comprise a protease inhibitor, preferably aprotinin which is also known under the brand name of Trasylol® (page 3, last paragraph). Typical methods of administration are disclosed at page 5, first full paragraph, including intravenous. The amount to be administered is described in terms of ng/ml of blood over 48 hours by Althaus rather than the resulting microgram/kg body weight instantly claimed. These different dosage measurements are not clearly comparable. Claim 6 does not state how much is administered ("an amount sufficient"), but rather describes the resulting level in the treated patient. Thus, while Althaus provides the usual administrative dosage information, the therapeutic level is claimed instantly. Short of testing, there is no way to determine what dosage rate gives rise to a given level. Clearance, tolerance and other factors are known in the art to effect the level of a therapeutic at any given dosage. These factors are also known to change during therapy, and hence the levels of a therapeutic are usually monitored. Since therapeutic levels are desired both in the instant application and in Althaus, it can be assumed that a "sufficient amount" of the composition will be administered to attain this level and therefore this is inherent in the process of treatment suggested by Althaus.

Unger et al. (EP 731,108) discloses interval treatment of oligodendrocytes in multiple sclerosis with pharmaceutical compositions of human NGF-ß for the improved remyelination in nerve fibers compared to continuous treatment.

Unger et al. (1995) disclose that NGF (human recombinant) infusion (intracerebral or intraventricular) remediates lysolecithin induced demyelination and regeneration of nerve fibers in pig brains. The demyelination is said to be a model for demyelinating and secondary inflammatory diseases such as MS (a known human disease) and suggests the therapeutic potential of NGF.

A person of ordinary skill in the art at the time the invention was made would have been motivated to administer NGF as taught by Kramer et al. (1995) to humans (with human NGF) and in appropriate amounts with protease inhibitor as indicated by Urschel et al. (1990), Althaus (WO 9303140, Unger et al. (EP 731,108) and Unger et al. (1995) because it is well known in the art that cognate specific proteins are preferably used. Further it involves nothing more than routine optimization of a result effective variable, the amount of NGF, to determine the effective dosage for a treatment already suggested by the art.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to administer NGF to humans in an amount sufficient to suppress demyelination.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 571-272-0925. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon P Weber, Ph.D.
Primary Examiner
Art Unit 1651

JPW
6 February 2004